

REMARKS

35 USC §112

MK-0677 versus Ghrelin

As described in the signed declaration (filed January 29, 2008) MK-0677 is a well known and accepted analogue of ghrelin. Furthermore, data described in Arnold et al (submitted January 29, 2008) using ghrelin has confirmed the results obtained with MK-0667 according to the application, ruling out that the discrepancies observed are due to the use of MK-0667 and not wild type ghrelin (see previous response).

Undue experimentation - prophylactically effective - claim 38

The amended claim 38 is limited to treatment or inhibition by administration during or after gastrectomization, thus the treatment is directed to an individual who is actually subject to a gastrectomy. Consequently, the claim does not relate to prophylactic treatment nor requires undue experimentation.

Therefore in conclusion the application fulfils the written description requirements enabling a person skilled in the art to make and use the invention.

35 USC §103

Independent claims 1 and 38 relate to treatment of individuals subjected to a gastrectomy.

The prior art documents relied on by the Examiner, teach that gastrectomy stimulates weight loss and that ghrelin stimulates appetite. Noticeable, these secondary references teach that ghrelin stimulates appetite in healthy individuals, not in gastrectomized individuals. Further documents teaching away from the invention must also be considered. Asakawa clearly agrees with Wren, to the fact that ghrelin stimulates appetite in a normal individual, but Asakawa further discloses that ghrelin does not have the same activity in vagotomised individuals (for detailed description see previous response).

The prior art references are to illustrate the knowledge and

starting point for the skilled person, when considering a treatment of loss of body weight (etc.) for gastrectomized individuals. The digestive system of a vagotomized individual is impaired, whereas the digestive system of a healthy individual is unimpaired. A skilled person would consider the digestive system of a gastrectomized individual to resemble that of vagotomized individuals more than healthy individuals. Therefore the skilled person must take the teaching of Asakawa into account and consequently the Asakawa reference is relevant for determining obviousness of the present invention also in the present situation where the claims are not limited to an individual subjected to vagotomy.

The above arguments do not relate to the question of whether a gastrectomy may or may not include a vagotomy. The fact that this is often the situation does not influence the claims, but it does influence the person skilled in the art, as he when assessing the expectation of success for using ghrelin for treatment of weight loss in gastrectomized individuals, would take this knowledge into account. The knowledge that gastrectomy is often accompanied (deliberately or accidentally) by a vagotomy therefore further strengthens the teaching away by Asakawa.

In conclusion the prior art document in total, and in particular Asakawa, teaches away from the present invention and thus, claims 1 to 38 are non-obvious above the cited prior art documents.

The above arguments also apply for any combination of primary and secondary documents cited by the Examiner as Asakawa is a relevant document and thus must be taken into account in any situation as it teaches away from the present invention.

Furthermore, the applicant has demonstrated unexpected results as described in the application supported by the previously filed declaration, by showing that the ghrelin analogue MK-0667 increases body weight and fat pad weight in gastrectomized rats.

Base on the above it is concluded that the invention as

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claimed is non-obvious.

Respectfully submitted,

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